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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,111	02/04/2002	Wayne L. Ryan	1003-015D1	6000
23369	7590	12/08/2004		
HOWREY SIMON ARNOLD & WHITE LLP 750 BERING DRIVE HOUSTON, TX 77057			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/067,111

Applicant(s)

RYAN ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 4, 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 22 October 2004.

Applicant's election with traverse of Group II, claims 39-46 in the reply filed on 22 October 2004 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper because the compositions of Group II, claims 39-46, are the analogous method claims to the composition claims of U.S. Patent 6,794,152. Thus, the Group I and II are part of the same class, namely 435/40.5. Thus, Applicants believe that the restriction is improper since the pending claims do not have a separate classification status. Applicant also argues that the search for the additional eighteen claims would not be burdensome, especially since the analogous composition claims to presently pending claims 39-46 have already been searched in U.S. Patent 6,794,152.

This is not found persuasive because the claims are drawn to a method using different compositions. These compositions have been shown to be different because they comprise different components, therefore, the method of using them would result in different effects. The fact that the allowed claims are analogous to the elected claims only serves to confirm that the non-elected claims are directed toward a different composition and method for using it. The claims of US patent 6,794,152 have been cross-referenced to 435/40.5, but are officially classified in 435/7.24. Furthermore, the search strategies for the two inventions are different and may overlap, but are not necessarily coextensive.

The requirement is still deemed proper and is therefore made FINAL.

*Claim Rejections - 35 USC § 112, first paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed toward a method for preparing a sample of fresh human whole blood by treating the sample with an aqueous reagent comprising a lipoprotein, an erythrocytes lysing agent, a salt and a preservative such as DU, IDU and oxazolidine. Such a method does not have support in the specification as originally filed. The specification lacks a definition for "fresh"; therefore, it is unclear how this term has been defined. The specification teaches at page 6, line 27 that the composition may be used to treat blood of humans; however, it does not specifically teach *fresh human whole blood*. At page 7, line 5, the specification disclose the use of a fresh sample of blood, however it does not specifically state how a sample is defined as *fresh*. Page 8 and examples 1-3 teaches the analysis of human blood samples 48 hours after they are drawn, however, it does not make clear that such a sample would be defined as *fresh*, nor does it have any discussion of the sample being a *whole blood* sample.

*Claim Rejections - 35 USC § 112, second paragraph*

4. Claims 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 49 are vague with respect to the part b because it is unclear what is meant by "a fluorescent label associated with a known antibody". Is the label attached to the antibody? Furthermore, it is unclear if the labeled antibody binds to the leukocytes in the sample. It is recommended that part b be amended as follows: "binding said at least one leukocyte with a fluorescently labeled antibody; and"

Claim 42 does not further limit claim 39.

*Conclusion*


5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
12/6/04